

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ : MDL NO. 1203
FENFLURAMINE/DEXFENFLURAMINE) :
PRODUCTS LIABILITY LITIGATION :
THIS DOCUMENT RELATES TO: :
SHEILA BROWN, et al. :
v. :
AMERICAN HOME PRODUCTS :
CORPORATION : NO. 99-20593

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

Bartle, C.J.

July 2, 2010

Class Counsel and Wyeth¹ jointly move for approval of the Tenth Amendment to the Diet-Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement"). Movants assert the Tenth Amendment is fair and reasonable.

I.

To understand the Tenth Amendment, recitation of some history is required. On September 15, 1997, two prescription diet drugs marketed and sold by Wyeth, Pondimin (fenfluramine) and Redux (dexfenfluramine), were withdrawn from the market after it was determined that they may cause valvular heart disease. On

1. Prior to March 11, 2002, Wyeth operated under the name American Home Products Corporation. On October 16, 2009, Wyeth became a wholly-owned indirect subsidiary of Pfizer, Inc. ("Pfizer"). On November 9, 2009, Wyeth changed its name to Wyeth LLC. We refer to Wyeth LLC as "Wyeth."

October 12, 1999, a class action complaint was filed in this court for the purpose of settling thousands of claims by persons in the United States who ingested these diet drugs. Shortly thereafter, on November 18, 1999, Class Counsel and Wyeth entered into a class action settlement agreement, which subsequently was approved by this court. See Pretrial Order No. 1415 (Aug. 28, 2000). The Settlement Agreement resolved the claims of, and provided several potential benefits to, class members, as well as their consortium claimants. Pursuant to the Settlement Agreement, an aggregate global settlement fund of \$3.75 billion was created.

Originally, two funds, known as Fund A and Fund B, were established to pay for different types of benefits to class members. A trust, known as the AHP Settlement Trust (the "Trust"), was created to hold Fund A and Fund B and to administer the payment of benefits. Settlement Agreement § III.A.1. Of the \$3.75 billion settlement fund, \$1 billion was allocated to Fund A to provide free echocardiogram screening, purchase price refunds and medical monitoring, or cash to fund medical services. Additionally, \$200 million was placed in an escrow account for the purpose of paying attorneys' fees.

Fund B provided compensatory damages to class members who were diagnosed with valvular heart disease. These benefits are awarded according to four damage "Matrices" set forth in the Settlement Agreement and are known as "Matrix Compensation Benefits." After making an initial deposit of \$25 million into

Fund B, Wyeth was required to make deposits as requested by the Trust on a quarterly basis to pay claims which qualified for payment during that period. Settlement Agreement § III.C. Wyeth's obligation to pay monies into Fund B was limited to the "Maximum Available Fund B Amount" ("MAFBA"). Settlement Agreement § III.C.4. The MAFBA is calculated by adding the "Fund B Accretions" to \$2.55 billion (which is the amount remaining in the \$3.75 billion settlement fund after providing the \$1.2 billion for Fund A) and then subtracting all amounts paid by Wyeth into Fund B. Settlement Agreement § I.1. Fund B Accretions are calculated quarterly and equal 1.5% of the MAFBA as of the close of the preceding quarter. Pursuant to the original Settlement Agreement, Fund B was secured by a "Security Fund" consisting of cash and high-grade securities having a principal value of \$370 million. Settlement Agreement § III.E.2.

At the end of 2017, Wyeth's payment obligations with respect to Fund B change. At that point, the Trust is required by the Settlement Agreement to "cause an actuarial determination to be made" as to the amount of funds necessary to compensate class members who have qualified or are likely to qualify for Fund B benefits in the future, as well as the accompanying administrative costs. Id. at III.C.4.b.i. Absent a challenge to the Trust's actuarial determination, this amount would become the "Final Projected Amount." Id. at III.C.4.b.iii. After paying the Final Projected Amount, Wyeth's funding obligations with

respect to Fund B end, and the Security Fund terminates. Id. at III.C.4.a., III.E.3.

In December, 2002, with the approval of the Fifth Amendment, Funds A and B were merged into one fund, known as the "Settlement Fund," from which all benefit payments were to be made. See Pretrial Order No. 2677 (Dec. 10, 2002), aff'd In re: Diet Drugs Prods. Liab. Litig., No. 02-4581, 2004 WL 326971 (3d Cir. Feb. 23, 2004); Settlement Agreement § III.B.4. The amount in Fund A became available to pay Matrix Compensation Benefits that previously were paid only out of Fund B. Settlement Agreement § III.B.4.d. Additionally, the Fifth Amendment increased the amount of the Security Fund by \$535,215,225, which represents 80% of the amount that was transferred from Fund A to the Settlement Fund. Settlement Agreement § III.E.2.

In March, 2005, the Settlement Agreement was amended a seventh time in response to concerns that Wyeth's funding obligations would be exhausted prior to payment of all valid claims and to deal with the procedural difficulties of administering a 100% audit of more than 40,000 claims for Matrix Compensation Benefits. See Pretrial Order No. 4567 (March 15, 2005). Pursuant to the Seventh Amendment, a Supplemental Class Settlement Fund was created to receive an additional \$1.275 billion from Wyeth. These funds were held and administered by a Fund Administrator that is separate from the Trust. We previously described the Seventh Amendment as follows:

Generally, the Seventh Amendment provides for the payment of: (1) reduced Matrix Compensation Benefits to eligible class members who have submitted Matrix level I and II claims; and (2) \$2,000 payments to class members who are found ineligible for Matrix Compensation Benefits, who withdraw their claims, or who are diagnosed as having only FDA Positive or mild mitral regurgitation. Class members who are eligible for Matrix Compensation Benefits will be paid based on a Relative Payment Grid, which assigns values based on medical condition, age at first diagnosis, duration of diet drug use, and the presence of alternative causation factors. [citation omitted]. In addition, these class members and those who have FDA Positive or mild mitral regurgitation are guaranteed additional payments if they develop higher level diseases. [citation omitted]. Wyeth will also offer those who participate in the Seventh Amendment a "surgery guarantee." [citation omitted]. This will extend to claimants the prospect of future compensation should their VHD progress to the point where surgery is required.

Pretrial Order No. 4567.

The Seventh Amendment created a "Seventh Amendment Security Fund" to provide additional security for the payment of claims submitted by Category One and Category Two class members. It is composed of \$255 million in cash-equivalent securities and commercial paper. Settlement Agreement § VI. The Seventh Amendment Security Fund will terminate on June 30, 2012. Id. at VI.E.2.

II.

The Tenth Amendment proposes to accomplish a number of important objectives. If approved, the Tenth Amendment adds \$12.5 million to the Cardiovascular Medical Research and

Education Fund ("CMREF"). The CMREF was established by the Settlement Agreement to finance research and education regarding heart disease and was originally funded by the transfer of up to \$25 million from Fund A. Settlement Agreement § IV.A.3.a. The scope of CMREF's research was narrowed by the Fifth Amendment which directed the organization to target its efforts on the treatment and cure of primary pulmonary hypertension, a nearly always fatal disease that has been associated with diet drugs use. See Pretrial Order No. 2677. Following the approval of the Fifth Amendment, the CMREF supported the creation of and funded the development of the Pulmonary Hypertension Breakthrough Initiative ("PHBI"), which is composed of 13 university-affiliated medical institutions. Dr. Stuart Rich, a member of the Research Advisory Committee of CMREF, states in his declaration that the "PHBI consortium has implemented a novel, collaborative research model in which the explanted lung tissue of PPH [primary pulmonary hypertension] patients and control patients undergoing lung transplants, together with blood samples and phenotypic information, are collected, preserved and disseminated for genetic, proteomic, cellular, tissue and other studies." The research presented by the PHBI has been "groundbreaking" and "has produced novel and exciting discoveries about the molecular basis of PPH." The current funding provides for the operations of the CMREF to continue until 2012. The proposed Tenth Amendment requires Wyeth to contribute an

additional \$12.5 million to CMREF to allow it to continue its important medical research regarding PPH.

Second, the proposed Tenth Amendment deletes Sections III.C.4.a and III.C.4.b of the Settlement Agreement. As briefly noted above, these provisions determine when Wyeth's obligation to make Settlement Fund payments is terminated. At the end of 2017, in lieu of continuing its periodic payments to the Settlement Fund, the Settlement Agreement generally requires Wyeth to make a final payment to the Settlement Fund. If the MAFBA exceeds the Final Projected Amount, then Wyeth is required to pay the Final Projected Amount as its final payment. If, however, the Final Projected Amount exceeds the MAFBA, then Wyeth is required to pay the MAFBA as its final payment.

If approved, the Tenth Amendment maintains the status quo, namely, it obligates Wyeth to continue making periodic payments into the Settlement Fund until the MAFBA is exhausted or there are no class members who remain eligible to receive Matrix Compensation Benefits. This eliminates the inherent uncertainty surrounding the calculation of the Final Projected Amount and the risk that future claims will go unfunded in the event that the Final Projected Amount is underestimated.

Third, the Tenth Amendment will initially reduce the amount of the Security Fund established by the Settlement Agreement to its pre-Fifth Amendment amount of \$370 million. Any amount in excess of \$370 million will be released to Wyeth. The

Tenth Amendment does not change the value of the Seventh Amendment Security Fund, which is \$255 million.

Beginning on July 1, 2012,² provisions V.C through V.J of the Tenth Amendment activate and govern the annual calculation of the amount of the Security Fund. In short, these provisions require the Trust to calculate the average amount of Matrix Compensation Payments made to certain class members during a specific time period. The amount of the Security Fund beginning on July 1, 2012 and continuing thereafter will be a variable of that average. For example, for the period from July 1, 2012 through June 30, 2013, the "Security Fund shall be in an amount equal to six times the Average 2015 Claimant Payment Total computed for the three-year period from 2009 to 2011."³ Tenth Amendment § V.D.1. For the period beginning February 16, 2016, the Security Fund "shall be in an amount equal to the greater of:

2. This is six months after the last date on which Category One and Category Two claimants may qualify for further Matrix benefits. Category One and Category Two class members were created by the Seventh Amendment. Category One "includes claimants who have submitted Matrix Level I and II claims which have not been adjudicated." Pretrial Order No. 4567. Category Two includes any claimants who have timely registered with the Trust by May 3, 2003 and have had "within the Screening Period an echocardiogram demonstrating mild or greater regurgitation of either the aortic valve or the mitral valve and who would qualify based on these conditions potentially for back-end opt-out rights or Matrix payment rights in the future." Id.

3. The "2015 Class Members" are "all Diet Drug Recipients (or the legal representatives of Diet Drug Recipients) who: (a) timely registered for Matrix Compensation Benefits from the Trust; (b) are not Category One Class Members; and (c) are not Category Two Class Members."

(1) six times the Average Age 80 Claimant Payment Total computed by the Trust for that year ... or (2) \$10 million."⁴ After December 31, 2018, the Security Fund may be terminated if the court finds that it is no longer reasonably necessary.

Fourth, the Tenth Amendment formally acknowledges that "Fund A's purposes have been met." Given that the deadlines to register for Cash/Medical Services benefits and purchase price refunds expired on May 3, 2003 and August 1, 2002, respectively, the Tenth Amendment states that the Trust shall not process or pay any claims for these benefits after December 31, 2011, except in certain circumstances.

Fifth, the proposed Tenth Amendment contains a guarantee from Pfizer, of which Wyeth became a wholly-owned indirect subsidiary on October 16, 2009. Pfizer "absolutely, unconditionally and irrevocably guarantees the full and punctual payment when due [...] of the deposits into the Settlement Fund required under Section III.C of the Settlement Agreement relating to Matrix claims, up to the Maximum Available Fund B Amount, pursuant to the terms of the Settlement Agreement[.]"

Finally, for purposes of calculating the MAFBA, there will be no Fund B Accretions occurring after December 31, 2011 if the Tenth Amendment is approved. See Settlement Agreement § I.1.

4. The "Age 80 Class Members" are "all Diet Drug Recipients (or the legal representatives of Diet Drug Recipients): (a) who have been determined ... to have developed a Matrix Level condition ... by the earlier of December 31, 2015, or the date on which such Diet Drug Recipient reaches the age of 80; and (b) who were 2015 Class Members at the time of such determination."

III.

Rule 23(e) of the Federal Rules of Civil Procedure provides that the "claims, issues, or defenses of a certified class may be settled, voluntarily dismissed, or compromised only with the court's approval." Fed. R. Civ. P. 23(e). The court may approve it "on finding that it is fair, reasonable, and adequate." Fed. R. Civ. P. 23(e) (2). We previously applied the "fair, reasonable, and adequate" standard when approving the Fifth, Sixth, Seventh, and Ninth Amendments. See Pretrial Order Nos. 2677, 2778, 4567, 5398.

The following nine factors guide our analysis of whether an amendment is fair, reasonable, and adequate:

- (1) the complexity, expense and likely duration of the litigation ...;
- (2) the reaction of the class to the settlement ...;
- (3) the stage of the proceedings and the amount of discovery completed ...;
- (4) the risks of establishing liability ...;
- (5) the risks of establishing damages ...;
- (6) the risks of maintaining the class action through the trial ...;
- (7) the ability of the defendants to withstand a greater judgment;
- (8) the range of reasonableness of the settlement fund in light of the best possible recovery ...;
- (9) the range of reasonableness of the settlement fund to a possible recovery in light of all the attendant risks of litigation ...

Girsh v. Jepson, 521 F.2d 153, 157 (3d Cir. 1975).

Our Court of Appeals explained, when reviewing our approval of the Sixth Amendment to the Settlement Agreement, that one "purpose for which it is appropriate to approve such an amendment is adjusting for changed circumstances, particularly in

light of the parties' experience in implementing the agreement."
In re Diet Drugs Prods. Liab. Litig., 385 F.3d 386, 392 (3d Cir. 2004). Here, Wyeth and Class Counsel are doing just that. The Settlement Agreement was approved by this court nearly ten years ago, in August, 2000. Significant changes have taken place since that time. By the end of the year in 2009, the Fund Administrator had distributed nearly the entire \$1.275 billion Supplemental Class Settlement Fund to pay class members eligible for benefits under the Seventh Amendment. Further, Martin Rudolph, the court-appointed Trustee of the AHP Settlement Trust, reports that as of the end of 2009, the Trust had paid \$3,092,193,607 in benefits and administrative costs under the terms of the original Settlement Agreement. This included \$567,926,582 in Fund A benefits and \$2,076,469,960 in Matrix Compensation Benefits, and \$447,797,065 in administrative costs. As evidenced by the benefits paid to date, the claims process has certainly reached its apex and is now slowing down.

The complexity, expense, and duration of this litigation has been monumental. The proposed Tenth Amendment strives to simplify the litigation going forward in several respects. First, it eliminates the provisions of the Settlement Agreement that would require Wyeth to make one final payment in 2018 to fund future Matrix Compensation Benefits through the termination of the Settlement, which the parties have estimated as being in 2063. If these provisions remained, the parties would be required to estimate the amount of funds necessary to

compensate class members' future benefit payments for decades. The Tenth Amendment eliminates the guess work involved with this procedure and continues the "pay-as-you-go" regime that is currently in place. Specifically, Wyeth is obligated under the Tenth Amendment to continue to fund payments for Matrix Compensation Benefits until there are no more eligible class members or until reaching the MAFBA limitation that is in effect as of December 31, 2011. We find that the first Girsh factor, examining the "complexity, duration and expense of the litigation," weighs in favor of approving the amendment.

The second Girsh factor is the "reaction of the class," which "attempts to gauge whether members of the class support the settlement" or, in this case, the amendment. In re Prudential Ins. Co. of America Sales Practices Litig., 148 F.3d 283, 318 (3d Cir. 1998). Two groups have filed objections. A group of 35 Matrix claimants and one Seventh Amendment member, collectively represented by attorney Joe Simon (the "Simon Claimants"), object on several bases. First, they assert that notice of the proposed Tenth Amendment must be given to any class member that could be affected by the changes it implements. Additionally, they assert that the notice should warn of Pfizer's conduct relating to products other than the diet drugs, as well as remind class members of already-noticed cut-off dates for certain benefits under the Settlement Agreement, such as payment for heart valve repair and/or replacement surgery.

Initially, we note that we are dealing here with notice in connection with an amendment to the Settlement Agreement. Notice in this circumstance is only required where the amendment to the settlement agreement would have a material adverse effect on the rights of class members. In re: The Prudential Ins. Co. of America Sales Practices Litig., 962 F. Supp. 450, n.10 (D.N.J. 1997); aff'd 148 F.3d 283 (3d Cir. 1998). Rather than having a material adverse effect on class members, the proposed Tenth Amendment provides many additional benefits, including additional funding for research relating to PPH and a guarantee from Pfizer regarding Wyeth's continued payment obligations under the Settlement Agreement. Most importantly, however, notice of the proposed Tenth Amendment, along with an opportunity to object, was supplied to representatives of all class members with active cases in MDL No. 1203. We provided similar notice in connection with the Fifth, Sixth, Eighth, and Ninth Amendments to the Settlement Agreement. Our Court of Appeals rejected a challenge to such notice in connection with the Fifth Amendment. In re: Diet Drugs Prods. Liab. Litig., No. 02-4581, 2004 WL 326971 (3d Cir. Feb. 23, 2004). It held that this issue was a matter within our discretion and no abuse of such discretion occurred. Id. at *5. We hold that additional notice, beyond that already given, is not required.

The Simon Claimants next object to the provisions of the Tenth Amendment which eliminate the calculation of the "Final Projected Amount" and continue the "pay-as-you-go" payment

system. They are concerned that Pfizer may encounter financial instability in the future and be unable to meet its payment obligations. The Simon Claimants highlight that Pfizer has pleaded guilty to unrelated, criminal conduct in the past. Furthermore, they question the joint claim of Class Counsel and Wyeth that the calculation of the Final Projected Amount will be subject to inherent uncertainty.

Class Counsel and Wyeth counter that adequate security is in place under the proposed Tenth Amendment. Initially, the Security Fund will be restored to its original \$370 million. This was the original amount of the Security Fund at the time of approval of the Settlement Agreement. They also highlight that the Seventh Amendment Security Fund, which stands at \$255 million, remains in place until June 30, 2012. Thereafter, the amount in the Security Fund will increase or decrease based on formulas designed to match the value of the Security Fund with a multiple of the likely aggregate payment needed for the payment of remaining Matrix Compensation Benefits. Moreover, Pfizer has provided a guarantee to meet Wyeth's funding obligations under the Settlement Agreement.

We agree with Class Counsel and Wyeth that the proposed Tenth Amendment provides adequate and sufficient security for the payment of future Matrix Compensation Benefits and costs of administration, even though the size of the Security Fund will be reduced to its original \$370 million level and then fluctuate based on the formulas set forth in the Amendment. Under the

Seventh Amendment, approximately 40,000 Matrix Level I and II claims were resolved and, as of December 31, 2009, the Trust had paid Matrix Compensation Benefits to more than 5,000 eligible class members. Since the Seventh Amendment was presented for approval, the Trust has paid annually an average of \$156 million in Matrix Compensation Benefits and administrative costs. Over the last two years, however, the amount of Matrix Compensation Benefits and administrative costs have averaged only \$72 million. Additionally, as of December 31, 2009, 77 Matrix claims with a value between \$16 million and \$22.4 million had passed audit and will be paid after the resolution of liens and the completion of post-audit processing steps. Based on the foregoing, it appears that the bulk of the claims have been processed and the number of claims being submitted for Matrix Compensation Benefits has decreased. Thus, restoring the Security Fund to its original value of \$370 million, which under the Tenth Amendment will remain in place until June 30, 2012, and then increasing or decreasing the amount in the Security Fund based on the aggregate amount needed to pay remaining Matrix Compensation Benefits is reasonable. Moreover, despite the protestations of the objectors, the guarantee of Pfizer, which posted revenues of over \$50 billion in 2009, gives the class added protection.

Strangely, the Simon Claimants assert that the PPH research being conducted by the CMREF does not benefit class members because the Settlement Agreement does not resolve PPH

claims. They also seemingly question the link between PPH and diet drug usage. We summarily reject these arguments.

Claimants Shirley Hough, Dawn Miklo, Nicholas Napora, and Judith Dahlka also filed a joint objection to the proposed Tenth Amendment. Their objection, however, does not raise any specific points with respect to the Tenth Amendment but instead argues that the claimants under the Seventh Amendment should receive additional compensation. We are at a loss as to why these claimants have filed objections regarding the Seventh Amendment in connection with the proposed Tenth Amendment.

In sum, the two objections filed in opposition to the proposed Tenth Amendment lack merit. The reaction of the class to the proposed Tenth Amendment is favorable.

The third Girsh factor requires that we consider the stage of the proceedings and amount of discovery completed. We have previously noted that this factor is more important to analyzing a settlement, as opposed to an amendment to an already-approved settlement. The parties to this decade-long litigation have ample experience dealing with the myriad of issues that have arisen since its inception. This experience provides a solid basis for the proposed Tenth Amendment.

The fourth and fifth Girsh factors "survey the possible risks of litigation in order to balance the likelihood of success the potential damage award if the case were taken to trial against the benefits of an immediate settlement." In re Prudential, 148 F.3d at 319. The sixth Girsh factor evaluates

the risks of maintaining the class action through trial. These criteria are more helpful in determining the fairness of a settlement, as opposed to an amendment. They do not advance our analysis of the fairness of the proposed Tenth Amendment given that a settlement has already been approved.

We must next evaluate the ability of Wyeth to withstand a judgment for an amount greater than what it is contributing pursuant to the proposed Tenth Amendment. We note that, on the whole, the Amendment obligates Wyeth to contribute an amount greater than originally anticipated under the Settlement Agreement. With the Amendment, Wyeth will contribute an additional \$12.5 million to CMREF so that it may continue its important research relating to PPH through additional grants. Further, Wyeth and Pfizer, through its guarantee, agree to continue funding the payment of Matrix compensation benefits beyond 2018, as opposed to making one final payment at that time. This provides greater security for the payment of future benefits and eliminates the cap that would accompany the payment of a lump sum final payment. We previously explained when approving the Seventh Amendment that the fact that Wyeth may be financially able to contribute an even greater amount than that anticipated does not mean it should be required to do so. Wyeth has been meeting its legal obligations to class members for over a decade. There appears to be no reason to require it to provide more to class members than they are legally entitled to receive under the Settlement Agreement.

The final two Girsh factors examine "whether the settlement is reasonable in light of the best possible recovery and the risks the parties would face if the case went to trial." In re Prudential, 148 F.3d at 322. Wyeth and Class Counsel highlight the difficulty of accurately predicting the amount and level of claims that will be presented to the Trust after 2017. This presents a risk that the estimate of the Final Projected Amount will be wrong and class members will go uncompensated due to a shortage of funds. The proposed Tenth Amendment eliminates this risk by requiring Wyeth and Pfizer to continue the pay-as-you-go system whereby Wyeth makes periodic payments to the Trust to fund Matrix compensation benefits. This weighs in favor of approving the proposed Tenth Amendment.

IV.

Accordingly, the Tenth Amendment to the Nationwide Class Action Settlement Agreement will be approved as fair, adequate, and reasonable.